Remarks

Applicants have cancelled claims 90-114, 116-120, and 128-131 without prejudice or disclaimer in favor of new claims 141-172. New claims 141-172 correspond essentially to the subject matter of previous claims 91, 93-97, 99, 101-114, 116-120, and 128-131, as described further in Section II below. New claims 141-172 find support throughout the specification and claims as originally filed, and thus no new matter has been added.

New claims 141-172 are pending.

I. Rejection of the Claims Under 35 U.S.C. § 101

Claims 90-114, 116-120 and 128-131 were rejected under 35 U.S.C. § 101. In particular, the Examiner alleged that:

> the specification fails to teach a correlation between ECA activity and asthma. It is also noted that the Hirashima et al (2000) reference which teaches the correlation between ECA and asthma was also a post-filing date reference. It is noted that the therapeutic uses set forth in the references published after the instant filing cannot be relied upon for enablement of the instant specification, as what is known in the art after the instant filing date is of no consequence regarding what one of skill in the art believed as of the filing date. See In re Wright, 27 USPQ 1510, 1514 (Fed. Cir. 1993).
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> Paper No. 31, page 2.

Claims 90-114, 116-120, and 128-131 were also rejected under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility under 35 U.S.C. § 101. Paper No. 31, page 3..

In response, Applicants respectfully disagree and traverse. Applicants particularly disagree with the Examiner's assertion regarding the use of post-filing date references, as the Examiner's argument and cited authority are directed to enablement, rather than to utility. It is well-established that post-filing date references and subsequently-generated data (*e.g.*, Sato and Hirashima) can be used to support the credibility of a utility asserted in the specification. As the Federal Circuit held in *In re Brana*, evidence dated after the filing date "can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." 51 F. 3d. 1560, 1567 at n.19 (Fed. Cir. 1995). Such evidence "goes to prove that the disclosure was in fact enabling when filed (*i.e.*, demonstrated utility)." *Id., citing In re Marzocchi*, 439 F2d. at 224 n.4, 169 U.S.P.Q. at 370 n.4. Indeed, the Utility Examination Guidelines in the M.P.E.P. specifically contemplate the use of such additional data:

> In such a case, the examiner should challenge the use and require sufficient evidence of operativeness. The purpose of this authority is to enable an applicant to cure an otherwise defective factual basis for the operability of an invention. Because this is a curative authority (e.g., evidence is requested to enable an applicant to support an assertion that is inconsistent with the facts of record in the application), Office personnel should indicate not only why the factual record is defective in relation to the assertions of the applicant, but also, where appropriate, what type of evidentiary showing can be provided by the applicant to remedy the problem.
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> M.P.E.P. § 2107.02(V) at 2100-41 to 42.

Thus, as the Examiner's basis for not addressing the substance of Applicants' previously submitted post-filing date evidence was incorrect, Applicants request that the Examiner specifically address the evidence in the next action, as described in M.P.E.P. § 2107.02.

Applicants have previously directed the Examiner to the teachings in the specification that Galectin 9 is useful for the diagnosis and treatment of, *inter alia*, asthma and Hodgkin's disease (*see* Response of 10/28/2002 at page 6), and have proven those teachings through post-filing date references, as permitted by the Utility Guidelines and the controlling Federal Circuit caselaw (*see* above). No more is required to satisfy 35 U.S.C. § 101. As the Patent Office and the Federal Circuit have repeatedly recognized, "there is no statutory basis to require disclosure of why an invention works or how is was developed. '[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.' *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989)." Utility Examination Guidelines at 1095-96 (Response to Comment 15). *See also Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980); *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995). Accordingly, Applicants respectfully submit that the rejection of claims 90-114, 116-120, and 128-131 under 35 U.S.C. § 101 has been obviated. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Further, the Federal Circuit has held that the utility requirement of 35 U.S.C. § 101 and the "how to use" requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches more than one specific, substantial, and credible utility of the claimed invention, thereby enabling the skilled artisan to use the claimed polypeptides.

Since the specification teaches more than one specific and immediate utility for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

II. Rejections of Claims 90, 92, 94-98, 100, 102-114, 116-120, 128-131, 133, and 136-140 Under 35 U.S.C. § 112, First Paragraph

Claims 90, 92, 94-98, 100, 102-114, 116-120, 128-131, 133, and 136-140 were rejected under 35 U.S.C. § 112, first paragraph. In particular, the Examiner alleges:

> [t]he specification, while being enabling for claims limited to the polypeptides comprising SEQ ID NO:4 and polypeptides consisting of amino acids 62-102, 226-259, and 197-308 of SEQ ID NO:4, does not reasonably provide enablement for polypeptides comprising 30 or 50 contiguous amino acids of SEQ ID NO:4, polypeptides comprising amino acids 62-102, 226-259, and 197-308 of SEQ ID NO:4, proteins comprising amino acid sequences which are at least 95% identical to SEQ ID NO:4 or proteins comprising amino acids which are encoded by polynucleotides that hybridize to SEQ ID NO:3 or the complement thereof.
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> Paper No. 31, page 3, point 6.

Preliminarily, Applicants note that the Examiner appears to have examined an earlier set of claims, as claims 133 and 136-140 were previously cancelled without prejudice, and contrary to the Examiner's statement on page 5, and claim 106 was amended in the response of 10/28/2002 to remove the phrase "having lactose binding activity," and to add the phrase "fragment ... of SEQ ID NO:4."

In light of the confusion over status of the pending claims, while Applicants maintain that claims 90, 92, 94-98, 100, 102-114, 116-120, and 128-131 fully complied with 35 U.S.C. § 112, first paragraph, Applicants have nonetheless canceled claims 90, 92, 94-98, 100, 102-114, 116-120, and 128-131 without prejudice or disclaimer in favor of new claims 141-172. Applicants reserve the right to file one or more continuing applications directed to the subject matter of the canceled claims. Applicants note that new claims 141-148 correspond essentially to the subject matter of previous claims 91, 93-97, and 128, and new claims 149-156 correspond essentially to the subject matter of previous claims 99, 101-105, and 129. Claims 141-156 also do not include the "at least 95% identical" or "lactose binding activity" phrases objected to by the Examiner. New claims 157-165 correspond essentially to the

subject matter of previous claims 106-113 and 130, with the substitution of the phrase "consisting of a fragment of the polypeptide of SEQ ID NO:4" for the previous phrase "comprising a fragment of the amino acid sequence of SEQ ID NO:4." Finally, new claims 166-172 correspond essentially to the subject matter of previous claims 114, 116-120, and 131, with the addition of the phrase "consisting of a fragment of the polypeptide of SEQ ID NO:4, wherein said fragment."

Thus, the language objected to by the Examiner is not present in the currently pending claims, rendering the instant rejections moot. Accordingly, Applicants respectfully request that the instant rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: April 14, 2003

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